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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,337	03/06/2000	SETTARA CHANDRASEKHARAPPA	15280-315100	2491

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/25/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/380,337

Applicant(s)
Chandrasekharappa et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 13, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-24, 26-30., 32-37, 38-42 is/are pending in the application.
- 4a) Of the above, claim(s) 9-18, 27-29, 34, 35, and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 19-24, 26, 30, 32, 33, 36, and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. The Amendment filed January 13, 2003 (Paper No. 18) in response to the Office Action of September 10, 2002 (Paper No. 17) is acknowledged and has been entered. Previously pending claims 7, 8, 31 have been canceled, claims 1, 6, 19, 24, 30, 36 have been amended and new claims 38-42 have been added. Claims 1-3, 5-6, 19-24, 26, 30, 32-33, 36, 38-42 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following Rejections are maintained:

Claim Rejections - 35 USC § 112

4. Claims 1-3, 5, 30, 32-33, 36-37 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in Paper No. 17 Section 6, pages 3-6.

Applicant argues that Guru et al (Mammalian Genome 10:592-596, 1999) and Manickam et al (Mammalian Genome 11:448-454, 2000) teach sequences with at least 60% identity to SEQ ID NO:2, wherein the references teach mouse and zebrafish sequences which encode amino acid sequences with 97%, 67% identity to human menin and Northern analysis showed that zebrafish Men1 gene is expressed. The argument has been considered but has not been found persuasive for the reasons previously set forth drawn to the teachings of Bowie, Burgess, Lazar and Bork.

5. Claims 1-3, 5-6, 19-24, 26, 30, 32-33, 36-37 remain rejected under 35 USC 112, first paragraph and claims 38, 41-42 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in paper No. 17, Section 10, pages 9-12.

Applicant argues that (a) Examiner does not provide proper evidence or reasoning as to why one of skill in the art could not reasonably expect that an RNA

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encoding menin would be expressed since the examples supplied are in fact drawn to proteins, regardless of the teachings in the art that the levels of protein can be controlled through translational as well as transcriptional mechanisms, (b) Wautot et al, (Int. J. Cancer, 85:877-881, 2000) teach that menin protein is expressed.

The arguments have been considered but have not been found persuasive because (a') there is no teaching that the protein encoded by SEQ ID Nos 1/3 is the expressed *in vivo* and although the references are drawn to proteins, it is clear that they are drawn to proteins that are not expressed or differentially expressed, (b') neither the reference nor the specification provide a nexus between the protein encoded by SEQ ID NO:1/3 and the menin taught by Wautot et al. Applicant's arguments have not been found persuasive and the rejection is maintained.

Further, it is noted that Applicant does not address the issue raised as to how to use the nucleic acid encoding SEQ ID NO:2 on pages 9-10 drawn to degenerate sequences and lack of known function for SEQ ID NO:2. For this reason as well, the rejection is maintained.

New Grounds of Objection

6. The amendment filed January 13, 2003 is objected to under 35 USC 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is (1) the substitution of "formamide" for "formalin with 1 mg of heparin", (2) probes in solution to nucleic acids immobilized on solid supports such as nitrocellulose filters or nylon membranes. Hybridization reactions in 50% formamide at 42°C are less harsh on nitrocellulose

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filters than is hybridization at 68° C in aqueous solution” in the paragraph starting on page 13, line 13 and continuing on page 14 through line 11.

Applicant is required to cancel the new matter in the response to this Office action.

Applicant states that the amendment to the specification adds no new matter because support for the amendment is provided in Sambrook et al which is cited in the specification at page 15, line 20 through page 16, line 31 and is incorporated by reference on page 54, lines 8-10. In Paper No. 18, Applicant points to the specific pages in Sambrook et al wherein support is provided for the amendments to the specification

Applicant argues, drawn to the amendment of the specification in the amendment filed June 19, 2002 drawn to “formamide”, that an amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. Applicant further argues that Examiner presents no evidence or reasoning as to why one of skill would not readily recognize that 50% formalin with 1 mg” should be corrected to “50% formamide”. The argument has been considered but has not been found persuasive because one of skill would not recognize the limitation in the claims as originally filed as an error and therefore neither evidence nor reasoning as to why one of skill in the art would not readily recognize that the error should be corrected is required. For Applicant’s convenience, Examiner attaches US Patent No. 6,107,462 which recites conventional hybridization conditions with wording identical to that recited in the specification as originally filed (see col 13, lines 11-16). Given the

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known, conventional, nature of the originally filed hybridization conditions it is clear that one of skill would not recognize an error in the specification.

Applicant further argues that the amendment contains no new matter because the use of formamide in standard hybridization solutions is well known and that since Sambrook, which discloses the general methods of use of the invention, is incorporated by reference - no new matter has been added. The argument has been considered but has not been found persuasive because although the newly added conditions are conventional and therefore obvious, obviousness is not the standard for the addition of new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). Further, a review of the specification reveals that Applicant generically pointed to a general reference that contains many citations of possible hybridization condition. As previously disclosed, mere reference to another publication is not incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 USC 112, first paragraph unless particular attention is directed to specific portions of the referenced document where the subject matter being incorporated may be found. In the instant case, the specification does not point to the particular hybridization conditions now claimed, as opposed to any of the other generic conditions recited in the general reference. There is nothing in the specification to lead one skilled in the art to these specific, now recited hybridization conditions in the publication. Applicant's arguments have not been found persuasive and Applicant is required to cancel the new matter in the response to this Office action.

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7. Claims 39-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. Claims 1-3, 6, 30, 32-33 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 17, Section 9, page 9 drawn to lack of written description for the limitation of hybridization conditions containing 50% formamide at 42 degrees centigrade.

Applicant's arguments drawn to the rejection of claim 8 are relevant to the instant rejection..

Applicant argues that the rejection is moot in view of the cancellation of the claim. The argument has been considered but has not been found persuasive because the limitations that broaden the scope of the invention are now recited in claims 1-3, 6, 30, 32-33.

Applicant further states that the amendments to the claims add no new matter because the added limitations are found in Sambrook et al which is incorporated by reference in the application. The argument has been considered but has not been found persuasive because a review of the specification reveals that Applicant generically pointed to a general reference that contains many citations of possible hybridization condition. As previously disclosed, mere reference to another publication is not incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 USC 112, first paragraph unless particular attention is directed to specific portions of the referenced document where the subject

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matter being incorporated may be found. In the instant case, the specification does not point to the particular hybridization conditions now claimed, as opposed to any of the other generic conditions recited in the general reference. There is nothing in the specification to lead one skilled in the art to these specific, now recited hybridization conditions in the publication. Applicant's arguments have not been found persuasive and Applicant is required to cancel the new matter in the response to this Office action.

9. Claim 4 appears to be free of the art and allowable.

10. Applicant's amendment necessitated the new grounds of rejection. Accordingly,

THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

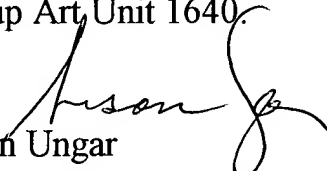
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.


Susan Ungar
Primary Patent Examiner
March 17, 2003